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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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EXAMINER

KUBELIK, ANNE R

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1638

DATE MAILED: 01/15/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | | |
|------------------------------|------------------------|--|---------------------|--|
| Office Action Summary | Application No. | | Applicant(s) | |
| | 09/856,979 | | HAMADA ET AL. | |
| | Examiner | | Art Unit | |
| | Anne R. Kubelik | | 1638 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on with the application is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>9</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-10 are pending.
2. The drawings are objected to for the reasons indicated on the accompanying form PTO 948. Corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance. See 37 CFR 1.85(a) and MPEP 608.02(b).
3. The title of the invention is not descriptive of the instant invention. A new title is required that is clearly indicative of the invention to which the claims are directed. Note that titles can be up to 500 characters long.
4. The abstract is not descriptive of the instant invention. A new abstract is required that is clearly indicative of the invention to which the claims are directed.

Claim Objections

5. Claims 2-3, 5 and 9-10 are objected to because of the following informalities:

An article is missing before "barnase" in claim 2, line 2, and before "Barstar" in claim 3, line 3.

In claim 5, "No:" should be replaced with --NO:--.

In claims 9-10 it is suggested that the phrase "being the same ... therefrom" be deleted and the phrase --, wherein the second promoter is the same as or different from the first promoter-- be inserted after "second promoter" in line 6.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-6 and 7-10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for promoters of SEQ ID NO:6 and 7, methods of using them to make male-sterile plants, and plants so obtained, does not reasonably provide enablement for promoters that are portions of SEQ ID NO:6 or modified versions of SEQ ID NO:7, methods of using them to make male-sterile plants, and plants so obtained. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are broadly drawn to plasmid vectors that have a T-DNA containing an anther-specific promoter operably linked to the barnase gene and an anther-specific promoter operably linked to the Barstar gene, a method of using them to produce male-sterile plants, and plants so obtained. The claims are also drawn to a multitude of promoters that comprise a part of SEQ ID NO:6 or modifications of SEQ ID NO:7.

The instant specification, however, only provides guidance for obtaining a 356 bp fragment (SEQ ID NO:7) of the rice E1 promoter (SEQ ID NO:6) by PCR amplification (pg 12-13); construction of a plasmid comprising the entire E1 promoter is operably linked to the Barstar gene and SEQ ID NO:7 operably linked to the barnase gene (pg 13); transformation of rice with the plasmid to produce male-sterile rice plants (pg 13-14).

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The instant specification fails to provide guidance for construction of other promoters that are portions of SEQ ID NO:6 or for construction of modified versions of SEQ ID NO:7.

Mutation of promoter sequences is unpredictable. Donald et al (1990, EMBO J. 9:1717-1726) in a mutational analysis of the *Arabidopsis rbcS-1A* promoter found that the effect of a particular mutation was dependent on promoter fragment length (paragraph spanning pg 1723-1724).

Identification of the functional parts of promoters is also unpredictable. Chen et al (2000, Sex. Plant Reprod. 13:85-94) teach that two promoters with similar expression patterns have major differences in the expression elements required for expression in various flower parts (pg 92, right column, last two paragraphs).

The region of a given promoter that has a specific activity cannot be predicted and involves the complex interaction of different subdomains (Benfrey et al, 1990, Science 250:959-966, see Abstract, Fig. 3-5). Even a very small region may be critical for activity, and the criticality of a particular region must be determined empirically (Kim et al, 1994, Plant Mol. Biol. 24:105-117, Tables 1-4, Abstract, Fig. 1-2).

As the specification does not describe the transformation of any plant with a construct using promoters that are portions of SEQ ID NO:6 or for construction of modified versions of SEQ ID NO:7, undue trial and error experimentation would be required to screen through the myriad of nucleic acids encompassed by the claims and plants transformed therewith, to identify those with male-sterility, if such plants are even obtainable.

Given the claim breath, unpredictability in the art, and lack of guidance in the specification as discussed above, the instant invention is not enabled throughout the full scope of the claims.

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8. Claims 1-5 and 7-10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to a multitude of promoters that comprise a part of SEQ ID NO:6 or modifications of SEQ ID NO:7. In contrast, the only promoter that comprises a part of SEQ ID NO:6 described in the specification is SEQ ID NO:7; no promoters that comprise modifications of SEQ ID NO:7 are described. Applicant does not describe other DNA molecules encompassed by the claims, and the structural features that distinguish all such nucleic acids from other nucleic acids are not provided.

The claims are broadly drawn to a multitude of plasmid vectors comprising a promoter operably linked to any RNase gene and a second promoter operably linked to any RNase inhibitor gene, and plants and plant cells transformed with the plasmids. In contrast, the only promoter described in the specification is SEQ ID NOs:6 and 7, the only RNase inhibitor gene described is Barstar and the only RNase gene described is barnase.

Hence, Applicant has not, in fact, described promoters that comprise a part of SEQ ID NO:6, RNase inhibitor genes and RNase genes within the full scope of the claims, and the specification fails to provide an adequate written description of the claimed invention.

Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed compositions, it is not clear that Applicant was in possession of the genus claimed at the time this application was filed.

See *Univ. of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed. Cir. 1997):

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The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA Accordingly, the specification does not provide a written description of the invention

and at pg 1406:

a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA," without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicted, does not suffice to define the genus because it is only an indication of what the genes does, not what it is.

See *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at page 1021:

A gene is a chemical compound, albeit a complex one, and ... conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials Conception does not occur unless one has a mental picture of the structure of the chemical or is able to define it by its method of preparation, its physical or chemical properties, or whatever characteristics sufficiently distinguish it. It is not sufficient to define it solely by its principal biological property, e.g., encoding human erythropoietin, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1-6, 8 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being

indefinite for failing to particularly point out and distinctly claim the subject matter that

Applicant regards as the invention. Dependent claims are included in all rejections.

Claim 1 lacks antecedent basis for the limitation "said plant" in line 7.

Claim 8 is indefinite in its recitation of "the sequence obtained by modifying ... one or more nucleotides". It is unclear which nucleotides are substituted, deleted or added and what the sequence of the claimed promoter is. Thus, the metes and bounds of the claim are unclear.

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Claim 10 is indefinite in its recitation of “transferred into the genome thereof”. It is unclear what is transferred into the genome of the plant cell. The second promoter” The second promoter/RNase inhibitor protein gene? Both I) and ii)? By position of the phrase in the sentence it is only the second promoter that is so transferred.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1-5 and 7-10 are rejected under 35 U.S.C. 102(b) as being anticipated by each of Michiels et al (WO 92/13956) and Michiels et al (1997, US Patent 5,639,948).

Michiels et al teach plasmid vectors that have a T-DNA containing an anther-specific promoter operably linked to the barnase gene and an anther-specific promoter operably linked to the Barstar gene, a method of using them to produce male-sterile plants, and rice, corn and tobacco plants so obtained (pg 20-33 of WO 92/13956 and column 9, line 46, to column 20, line 30 of '948). Among the promoters used was a 1690 bp part of the E1 promoter (pg 26, paragraph 1, of WO 92/13956 and column 14, lines 27-39 of '948). Michiels et al also teach the pT72, the pT42 and the pE1 promoters from rice (pg 15, paragraph 3, of WO 92/13956 and column 8, lines 19-46, of '948); all these would comprise a “part” of SEQ ID NO:6 of at least one nucleotide. The E1 promoter would comprise SEQ ID NO:7 and the pT72 and the pT42

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promoters would comprise SEQ ID NO:7 wherein the sequence is modified by substitution, deletion or addition of one or more nucleotides.

13. Claims 1-5 and 7-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Mariani et al (1998, US Patent 5,792,929).

Mariani et al teach plasmid vectors that have a T-DNA containing an anther-specific promoter operably linked to the barnase gene and an anther-specific promoter operably linked to the Barstar gene, a method of using them to produce male-sterile plants, and tobacco and rape plants so obtained (column 19, line 63, to column 21, line 14; claims 1-10, 24-32 and 80-90). Mariani et al also teach the pTA29, PTA13 and PTA26 promoters (column 19, line 63, to column 20, line 48); these promoters would comprise a "part" of SEQ ID NO:6 of at least one nucleotide.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over each of Michiels et al (WO 92/13956) and Michiels et al (1997, US Patent 5,639,948).

The claims are drawn to plasmid vectors that have a T-DNA containing an anther-specific promoter operably linked to the barnase gene and an anther-specific promoter operably linked to the Barstar gene, a method of using them to produce male-sterile plants, and plants so

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obtained. The claims are also drawn to such a method wherein the promoter consists of SEQ ID NO:7.

The teachings of Michiels et al are discussed above. Michiels et al also teach that the minimum region of the E1 promoter that can serve as an anther-specific promoter extends from 300-500bp upstream of the start codon (pg 18, paragraph 1 of WO 92/13956 and column 9, lines 39-42). Michiels et al do not disclose the specific 356 bp fragment that is SEQ ID NO:7.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the method of making male-sterile plants and the anther-specific E1 promoter taught by Michiels et al, to make the deleted version of the E1 promoter that is SEQ ID NO:7. One of ordinary skill in the art would have been motivated to do so because Michiels et al teach that the minimum region of the E1 promoter that can serve as an anther-specific promoter extends from 300-500bp upstream of the start codon (pg 18, paragraph 1). SEQ ID NO:7 corresponds to the 352 nucleotides upstream of the start codon, plus the start codon itself, and thus contains the region Michiels stated is essential for anther-specific expression (see sequence search report).

Conclusion

16. No claim is allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (703) 308-5059. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service at (703) 308-0198.

Anne R. Kubelik, Ph.D.

January 2, 2003

A handwritten signature in black ink, appearing to read "Amy Nelson", written in a cursive style.

AMY J. NELSON, PH.D
SUPERVISORY PATENT EXAMINER
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